DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 30, 2014

Pac-Dent International, Inc.
Ms. Wenying Zhu
Materials Engineer
21038 Commerce Point Drive
Walnut, CA 91789

Re: K141422
Trade/Device Name: ProFluro™ Fluoride Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Codes: LBH
Dated: June 30, 2014
Received: July 9, 2014

Dear Ms. Zhu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section III

Indications for Use Statement

510(k) Number (if known): K141422

Device Name: ProFluoro™ Fluoride Varnish

Indications for Use:

ProFluoro™ Fluoride Varnish is intended for use as:

- Professional treatment of dental hypersensitivity by occluding dentinal tubules with an adherent film

Prescription Use X OR Over-The-Counter Use _____

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Section IV

510(k) Summary

Submitter:
Pac-Dent International, Inc.
21038 Commerce Point Dr.
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Contact Person:
Wenying Zhu
Materials Engineer
909-839-0888 ext.111

Date Summary Prepared:
May 2014

Device Name

Trade Name: ProFluoro™ Fluoride Varnish
Common Name: Cavity varnish
Device Classification: Class II
Classification Product Code: LBH
Classification Name: Cavity varnish, per 21 CFR 872.3260

Predicate Device

Enamelast™ Fluoride Varnish (K132109)

Description of Device

ProFluoro™ Fluoride Varnish is a resin-based 5% sodium fluoride varnish applied to tooth surfaces with an applicator brush. Moisture from saliva cures the varnish and leaves a film on tooth to treat tooth hypersensitivity.

Indications for Use

- Professional treatment of dental hypersensitivity by occluding dentinal tubules with an

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adherent film

Summary of Biocompatibility Tests

The chemical components in ProFluoro™ Fluoride Varnish have been used in predicate device. Rosin and other rosin derivatives are used as adhesive agents in FDA approved dental varnishes. These include Duraflor®, Vanish™ Varnish, Enamel Pro® Varnish, Enamelast™ and the other fluoride varnishes. We believe these facts well support the compatibility of ProFluoro™ Fluoride Varnish, and the safety of the applicant device is substantially equivalent to the predicate devices in materials and technological properties.

The risk analysis provided above also shows that ProFluoro™ Fluoride Varnish is safe for its intended use.

No biocompatibility test is required to establish substantial equivalent to the predicate device.

Summary of Physical Tests

This 510(k) submission includes data from bench testing to evaluate the performance of ProFluoro™ Fluoride Varnish compared to predicate device Enamelast™ Fluoride Varnish. Properties evaluated include appearance, total fluoride (wt%), pH and film thickness.
It was concluded that ProFluoro™ Fluoride Varnish is substantially equivalent to and in some cases exceeding the predicate device in terms of physical properties.

Substantial Equivalence

In summary, this submission demonstrates that ProFluoro™ Fluoride Varnish is substantially equivalent in safety and effectiveness and performs equivalently or better to the identified predicated and comparable product for its intended use.